NO 7696145

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	K. Bortlik et al.
Appl. No.:	10/597,851
Conf. No.:	7063
Filed:	August 9, 2006
Title:	COMPOSITIONS CONTAINING CIS-ISOMERS OF A CAROTENOID COMPOUND AND PROCESS
Art Unit:	1655
Examiner:	C. Chen
Docket No.:	112701-746

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

Chemist, PhD in physio-chemistry, senior research scientist
Main scientific objective is to develop technological
processes for producing natural food active ingredients

2. I am one of the named inventors of the above-identified patent application and am, therefore, familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated January 30, 2008 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein, as well as the pending claims.

4. The present invention is directed, in part, toward compositions comprising a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound. One having

ordinary skill in the art would understand that a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound in accordance with the present claims is distinguishable from a carotenoid isolated or enriched from plants or animals.

5. A carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound is completely distinguishable from a carotenoid isolated or enriched from plants, animals or other natural sources. For example, the carotenoid-containing materials of the present claims are preferably carotenoid compounds such as lycopene, xeaxanthine, beta-cyrptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene. The carotenoid-containing materials are extracts, concentrates or oleoresins which are isolated, extracted, enriched or purified from a natural source such as a plant or vegetable material, a microorganism, a yeast or a product of animal origin. The *cis:trans* isomer ratio in such carotenoid compounds is low; in a selected tomato oleoresin, such ratio is 7:93. Therefore, the carotenoid-containing material is further subjected to a treatment to increase the *cis*-isomer content of the carotenoid. For example, the carotenoid-containing material is subjected to microwave irradiation if such material is an oleoresin. If an aqueous extract is used, a medium adapted to microwave irradiation may be used to increase the *cis*-isomers of the carotenoid compound, and the isomerisation may be performed under nitrogen in the presence of antioxidants. The carotenoid-containing material may then be further treated by solubilization of the *cis*-isomers in selected organic solvents followed by phase separation using centrifugation or filtration. Such treatment increases the *cis:trans* isomer ratio of the carotenoid up to at least 20:80.

6. Carotenoids are known to have beneficial medical effects such as alleviating chronic diseases. Current compositions containing carotenoids are available in the form of an extract, a concentrate or an oleoresin. However, the carotenoids present in such compositions are not sufficiently bioavailable. Therefore, the beneficial effects of such carotenoids cannot be fully realized.

7. With respect to the present disclosure, it has been found that enriching the *cis*-isomers of carotenoid compounds obtained from natural products increases the bioavailability

and/or bioefficacy of such compounds. Moreover, carotenoids with an enriched *cis*-isomer content are more soluble in lipids, less prone to crystallization, and have a lower tendency to aggregate. In contrast, carotenoid compounds isolated or enriched from natural sources are insufficiently bioavailable. By subjecting such carotenoid compounds to further treatment to enrich the *cis*-isomer content of the carotenoid compound, the bioavailability and/or bioefficacy of the enriched compound is better than that of the compound alone. Thus, a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound is completely distinguishable from a carotenoid isolated or enriched from plants, animals or other natural sources.

8. *Hartal* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound. Instead, *Hartal* only discloses isolating or enriching a carotenoid compound, lycopene, from a lycopene-containing oleoresin such as a tomato or watermelon. See, *Hartal*, column 2, lines 60-64; column 5, lines 36-60. However, a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound is distinguishable from a carotenoid compound that is merely isolated or enriched from a plant or animal. Enriching the *cis*-isomer content of a carotenoid involves further processing of the isolated or enriched carotenoid. Since *Hartal* only teaches an isolated or enriched carotenoid compound and fails to disclose or suggest enriching the *cis*-isomer content of the carotenoid compound anywhere in the disclosure, it cannot teach a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound.

9. *Rodriguez* also fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound. Instead, *Rodriguez* only discloses purifying carotenoids such as lutein and xeaxanthin from crude plant extracts. See, *Rodriguez*, Abstract; column 1, lines 7-9. Nowhere does *Rodriguez* disclose a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound. Since enriching the *cis*-isomer content of the carotenoid involves further processing of an isolated or enriched carotenoid compound, *Rodriguez* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound.

10. *Haigh* fails to disclose or suggest a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof. Instead, the only carotenoid *Haigh* discloses is beta-carotene. See, *Haigh*, Abstract; column 1, lines 5-15. Nowhere does *Haigh* disclose carotenoids such as lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, or phytoene. One of ordinary skill in the art would understand that there are structural differences between beta-carotene and the claimed carotenoids. Thus, *Haigh* fails to disclose or suggest a carotenoid compound selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 23.05.2008

Name:

PIERRE LAMBELET